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12
13 UNITED STATES DISTRICT COURT
14 CENTRAL DISTRICT OF CALIFORNIA
15

16 **SELF-INSURED SCHOOLS OF**
17 **CALIFORNIA**, on behalf of itself and all
18 others similarly situated,

19 Plaintiff,

20 v.

21 **MERCK & CO., INC.; MERCK**
22 **SHARP & DOHME CORP.;**
23 **SCHERING-PLOUGH CORP.;**
24 **SCHERING CORP.; MSP**
25 **SINGAPORE CO. LLC; PAR**
26 **PHARMACEUTICAL, INC.;**
27 **GLENMARK PHARMACEUTICALS**
28 **LTD.; GLENMARK GENERICS INC.,**
U.S.A.,

Defendants.

Case No. 8:18-cv-00487

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

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Plaintiff Self-Insured Schools of California (“Plaintiff” or “SISC”) brings this class action, on behalf of itself and all others similarly situated, against Merck & Company, Inc., Merck Sharp & Dohme Corporation, Schering-Plough Corporation, Schering Corporation, and MSP Singapore Company LLC (collectively, “Merck”), Par Pharmaceutical, Inc. (“Par”), and Glenmark Pharmaceuticals Limited and Glenmark Generics Inc., U.S.A. (collectively “Glenmark,” and collectively with Merck and Par, “Defendants”), based on personal knowledge as to itself and upon information and belief as to all other allegations, and alleges as follows.

I. NATURE OF THE ACTION

1. This is a civil antitrust action brought by Plaintiff on behalf of a proposed class of end-payors who indirectly purchased, reimbursed, or otherwise paid for Zetia (or ezetimibe). Zetia is a blockbuster brand-name drug sold by Merck to treat patients with high cholesterol. Plaintiff seeks overcharge damages and other relief arising out of an unlawful “reverse payment” agreement that resolved patent infringement litigation between Merck and Glenmark on the eve of trial (the “Agreement”). Under the Agreement, Glenmark agreed not to introduce a generic version of Zetia for six and a half years. In exchange, Merck agreed not to introduce its own “authorized” generic (a so-called “no-AG agreement”) during Glenmark’s first-filer 180-day exclusivity period. As a result of the Agreement, Merck unlawfully prolonged its Zetia monopoly and reaped windfall profits. Through the no-AG Agreement, Merck shared a portion of its ill-gotten gains (totaling hundreds of millions of dollars) with Glenmark.

2. While Defendants profited handsomely from their Agreement, consumers and third-party payors (also known as end-payors) paid inflated prices for brand and generic Zetia. A one-month supply of branded Zetia cost roughly \$300 per month before generics entered the market.¹ Today, with several generics on the market, a one-month

¹ See John LaMattina, Patent Expirations of Crestor and Zetia and the Impact on Other Cholesterol Drugs, *Forbes*, January 18, 2016, available at <https://www.forbes.com/sites/johnlamattina/2016/01/18/patent-expirations-of-crestor-and-zetia-and-the-impact-on-other-cholesterol-drugs/#b76d4222eff2>.

1 supply of generic ezetimibe costs as little as \$10, a reduction of nearly 97%. By delaying
2 generic competition, Defendants' unlawful Agreement has directly caused Plaintiff and
3 the Class to suffer antitrust injury in the form of overcharges.

4 3. Merck has sold Zetia since receiving FDA approval (and a 5-year exclusivity
5 period) in 2002. In 2006, Glenmark filed an Abbreviated New Drug Application
6 ("ANDA") to manufacture and sell a generic version of Zetia. Merck brought a patent
7 infringement suit against Glenmark. On April 24, 2009, the FDA granted tentative
8 approval to Glenmark to manufacture and sell a generic version of Zetia. On May 3,
9 2010, Par Pharmaceutical Companies, Inc. announced that its generic division, Par
10 Pharmaceutical, had entered into an exclusive agreement with Glenmark under which
11 Par had made a payment to Glenmark for the exclusive right to market, sell, and
12 distribute a generic version of Zetia in the United States. Under that agreement, Par
13 would share Zetia profits with Glenmark. One week later, Glenmark and Merck reached
14 their settlement agreement to resolve the patent litigation.

15 4. Several of the patents Merck listed in the FDA's "Approved Drug Products
16 with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book,"
17 were invalid for multiple reasons, including obviousness, inherent anticipation, and
18 inequitable conduct, among other reasons. Merck withheld information from the Patent
19 Office that would have shown that at least one of these patents, the RE'721 Patent, was
20 invalid in light of prior art. On information and belief, Merck acquired and asserted these
21 invalid and unenforceable patents to unlawfully extend its Zetia monopoly and to extract
22 concessions from potential generic competitors, including Glenmark and Par.

23 5. Defendants' actions constituted a contract, combination, and conspiracy in
24 restraint of trade in violation of the antitrust and competition laws of numerous states
25 and Section 1 of the Sherman Act, 15 U.S.C. § 1. Plaintiff brings this action on behalf of
26 itself and all others similarly situated seeking damages (trebled where allowed by
27 statute), expenses including reasonable attorneys' fees, and such other relief as the
28 Court deems equitable.

II. JURISDICTION, VENUE, AND INTRADISTRICT ASSIGNMENT

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. section 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds \$5,000,000, there are more than one hundred members of the Class, and at least one member of the proposed Class is a citizen of a state different from that of one of the Defendants. In addition, this Court has jurisdiction under 28 U.S.C. sections 1331 and 1337(a), and section 16 of the Clayton Act, 15 U.S.C. section 26.

7. Venue is proper in this District under 28 U.S.C. section 1391 because Defendants transact business in this District, and a substantial part of the interstate trade and commerce involved and affected by the violations of the antitrust laws was and is carried on in part within this District. Additionally, during the Class Period, Defendant Par Pharmaceutical maintained—and continues to maintain—offices and operations in Irvine, California, in this District. The acts complained of have and will continue to have substantial effects in this District.

III. PARTIES

A. Plaintiff Self-Insured Schools of California

8. Plaintiff Self-Insured Schools of California (“SISC”), is a Joint Powers Authority under California law that serves the interests of California public school district members, with its headquarters located at 2000 K Street, Bakersfield, CA 93303. SISC provides health benefit plans to approximately 300,000 members who reside in numerous locations in the United States. During the Class Period, SISC indirectly purchased and paid for brand and generic Zetia, other than for resale, manufactured by Defendants. During the Class Period, SISC paid and reimbursed more for Zetia than it would have absent Defendants’ anticompetitive conduct. As a result of the wrongful conduct alleged herein, SISC was injured in its business or property.

B. Merck Defendants

9. Defendant Merck & Company, Inc. is a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It is or was the parent company of defendants Merck Sharp & Dohme Corporation and MSP Singapore Company LLC.

10. Defendant Merck Sharp & Dohme Corporation is a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It is a subsidiary of Merck & Company, Inc. and the assignee of patents relevant to this lawsuit.

11. Defendant Schering-Plough Corporation was a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

12. Defendant Schering Corporation was a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It was a wholly owned subsidiary of Schering-Plough Corporation and the original assignee of the relevant patents.

13. In 2009, as part of the combination of Merck & Company, Inc. and Schering-Plough Corporation, Merck & Company merged into a wholly owned subsidiary of Schering-Plough Corporation. Schering-Plough Corporation subsequently changed its name to Merck & Company, Inc., and the company originally known as Merck & Company, Inc. changed its name to Merck Sharp & Dohme Corporation.

14. Defendant MSP Singapore Company LLC (“MSP”) is a company organized and existing under the laws of the state of Delaware, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, NJ 07033. MSP is a subsidiary of Merck & Company, Inc. and was the exclusive licensee of the relevant patents.

15. Defendant Merck & Company, Inc., Merck Sharp & Dohme Corporation, Schering-Plough Corporation, Schering Corporation, and MSP Singapore Company LLC are collectively referred to in this complaint as “Merck.”

C. Defendant Par

16. Par Pharmaceutical, Inc., an operating company of Endo International PLC, is a Delaware corporation with its headquarters located at One Ram Ridge Rd, Chestnut Ridge, NY 10977. Par Pharmaceutical markets, sells, and distributes ezetimibe, the generic form of Zetia, in the United States, under an agreement with Glenmark, which manufactures the ezetimibe. Par Pharmaceutical operates facilities in Alabama, California, Connecticut, Michigan, and New York. Endo Pharmaceutical PLC purchased Par Pharmaceutical Holdings, Inc. on September 25, 2015. Par Pharmaceutical Holdings, Inc. was the parent of Par Pharmaceutical Companies, Inc., which was the parent of Par Pharmaceutical, Inc., which specialized in developing, licensing, manufacturing, marketing, and distributing generic drugs in the United States. Defendant Par maintains an office at 9601 Jeronimo Road, Irvine, CA 92618.

D. Glenmark Defendants

17. Defendant Glenmark Pharmaceuticals Limited is a company organized and existing under the laws of India, with its headquarters at Glenmark House, B. D. Sawant Marg, Andheri (E), Mumbai 400 099, India, and its registered office at B/2 Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai 400 026, India.

18. Defendant Glenmark Generics Inc., U.S.A., formerly known as Glenmark Pharmaceuticals Inc., U.S.A., is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. It is a wholly owned subsidiary of Glenmark Pharmaceuticals Limited.

19. Defendant Glenmark Pharmaceuticals Limited and Glenmark Generics Inc., U.S.A. are collectively referred to in this complaint as “Glenmark.”

20. All of the Defendants’ wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by the Defendants’ various officers, agents, employees, or other representatives while actively engaged in the management of

the Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the Defendants.

IV. CLASS ACTION ALLEGATIONS

21. SISC, on behalf of itself and all others similarly situated indirect purchasers, seeks damages, measured as overcharges and trebled where available under applicable law, against Defendants based on allegations of anticompetitive conduct in the market for Zetia and its AB-rated generic equivalents.

22. SISC brings this action on behalf of itself and as a class action under Federal Rules of Civil Procedure 23(a) and (b)(2), seeking equitable and injunctive relief on behalf of a Class of indirect purchasers as representatives of a Class defined as follows (the "Nationwide Injunctive Relief Class"):

All persons and entities in the United States and its territories who indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price for Zetia or generic Zetia, other than for resale, from December 6, 2011, through the present (the "Class Period").

This class excludes: (a) Merck, Glenmark, and Par, including any predecessor or successor of Merck or Glenmark, or Par, and their officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (c) all persons or entities who purchased Zetia or generic Zetia for purposes of resale or directly from Merck, Glenmark, and Par, including any predecessor or successor of Merck, Glenmark or Par; (d) fully insured health plans (*i.e.*, health plans that purchased insurance covering 100% of their reimbursement obligation to members); (e) any "flat co-pay" consumers whose purchases of Zetia or generic Zetia were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price; (f) pharmacy benefit managers; and (g) any judges or justices involved in this action and any members of their immediate families.

1
2 23. SISC also brings this action on behalf of itself and as a class action under
3 Federal Rules of Civil Procedure 23(a) and (b)(3) seeking damages pursuant to the
4 antitrust, unfair competition, and consumer protection laws of the states and territories
5 identified below on behalf of the following class (the “Damages Class”):

6 All persons and entities in the United States and its territories
7 who indirectly purchased, paid, and/or provided
8 reimbursement for some or all of the purchase price for Zetia
9 or generic Zetia, other than for resale, from December 6, 2011,
through the present (the “Class Period”).

10 This class excludes: (a) Merck, Glenmark, and Par, including
11 any predecessor or successor of Merck or Glenmark, or Par,
12 their officers, directors, management, employees, subsidiaries,
13 and affiliates; (b) all federal and state governmental entities
14 except for cities, towns, municipalities, or counties with self-
15 funded prescription drug plans; (c) all persons or entities who
16 purchased Zetia or generic Zetia for purposes of resale or
17 directly from Merck, Glenmark, and Par, including any
18 predecessor or successor of Merck or Glenmark, or Par; (d)
19 fully insured health plans (*i.e.*, health plans that purchased
20 insurance covering 100% of their reimbursement obligation to
21 members); (e) any “flat co-pay” consumers whose purchases
22 of Zetia or generic Zetia were paid in part by a third-party
payor and whose co-payment was the same regardless of the
23 retail purchase price; (f) pharmacy benefit managers; and (g)
24 any judges or justices involved in this action and any members
25 of their immediate families.

26 24. The Nationwide Injunctive Relief Class and the Damages Class are referred
27 to generally as the “Class.”

28 25. Members of the Class are so numerous that joinder is impracticable.
Members of the Class are widely dispersed throughout the country. Plaintiff believes the
Class includes hundreds of thousands, if not millions, of consumers and thousands of
third-party payors.

1 26. Plaintiff's claims are typical of the claims of the members of the Class.
2 Plaintiff and all members of the Class were damaged by the same wrongful conduct by
3 Defendants, *i.e.*, they paid artificially inflated prices for branded and/or generic Zetia
4 manufactured by Defendants as a result of Defendants' wrongful conduct.

5 27. Plaintiff will fairly and adequately protect and represent the interests of the
6 Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

7 28. Plaintiff is represented by counsel who are experienced and competent in
8 the prosecution of class action antitrust litigation, particularly in the pharmaceutical
9 industry.

10 29. Questions of law and fact common to the members of the Class
11 predominate over any questions that may affect only individual Class members, because
12 Defendants have acted on grounds generally applicable to the entire Class.

13 30. Questions of law and fact common to the Class include:

14 a. whether Defendants' conduct constitutes a violation of the federal
15 and state laws listed below;

16 b. whether Defendants conspired to and did suppress generic
17 competition for Zetia;

18 c. whether, pursuant to the Agreement, Glenmark agreed to and did
19 delay its entry into the market with generic Zetia;

20 d. whether there are legitimate procompetitive justifications explaining
21 Glenmark's decision to delay its entry into the market with generic Zetia;

22 e. whether, pursuant to the Agreement, Merck agreed not to sell an
23 authorized generic during Glenmark's 180-day exclusivity period;

24 f. whether there are legitimate procompetitive justifications explaining
25 Merck's decision not to sell an authorized generic during Glenmark's 180-day
26 exclusivity period;

27 g. whether Defendants' challenged conduct harmed competition in the
28 market for Zetia and its AB-rated generic equivalents;

1 h. whether Defendants conspired to maintain Merck's market power in
2 the market for branded Zetia;

3 i. whether Merck possessed market power in the market for branded
4 Zetia;

5 j. whether, and to what extent, Defendants' conduct as alleged herein
6 caused antitrust injury to the business or property of Plaintiff and the members of the
7 Class in the nature of overcharges; and

8 k. the amount of aggregate overcharge damages paid by the Class.

9 31. Class action treatment is a superior method for the fair and efficient
10 adjudication of the controversy because, among other things, class treatment will permit
11 a large number of similarly situated persons to prosecute their common claims in a single
12 forum simultaneously, efficiently and without the unnecessary duplication of evidence,
13 effort and expense that numerous individual actions would engender. The benefits of
14 proceeding through the class mechanism, including providing injured persons or entities
15 with a method for obtaining redress on claims that might not be practicable to pursue
16 individually, substantially outweigh any difficulties that may arise in the management of
17 this class action.

18 32. Plaintiff knows of no difficulty to be encountered in the management of this
19 action that would preclude its maintenance as a class action.

20 **V. REGULATORY BACKGROUND**

21 **A. The Regulatory Structure for Approval and Substitution of Generic** 22 **Drugs**

23 33. Under the Federal Food, Drug, and Cosmetic Act (FDCA), a drug
24 manufacturer or other entity seeking to sell or market a new drug in the U.S. must first
25 obtain the approval of the FDA by filing a New Drug Application ("NDA"). 21 U.S.C.
26 §§ 301-392. The NDA must include specific data concerning the safety and effectiveness
27 of the drug, and it must identify any patent that allegedly claims either the approved drug
28 or approved methods of use of the drug and could reasonably be asserted against a

1 generic manufacturer who makes, uses, or sells a generic version of the brand drug prior
2 to the expiration of the listed patent(s). 21 U.S.C. §§ 355(a) & (b). When the FDA
3 approves an NDA, it publishes the patents identified by the brand manufacturer in
4 “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly
5 known as the “Orange Book.” Patents issued after NDA approval may be listed in the
6 Orange Book within thirty days of issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

7 34. The FDA relies completely on the brand manufacturer’s truthfulness about
8 patent validity and applicability, as it does not have the resources or authority to verify
9 the manufacturer’s patents for accuracy or trustworthiness. In listing patents in the
10 Orange Book, the FDA merely performs a ministerial act.

11 1. The Hatch-Waxman Amendments

12 35. The Hatch-Waxman Amendments, enacted in 1984, simplified the
13 regulatory hurdles for prospective generic manufacturers by eliminating the need for
14 them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term
15 Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A generic manufacturer
16 seeking approval to sell a generic version of a brand drug may instead file an Abbreviated
17 New Drug Application (“ANDA”). An ANDA relies on the scientific findings of safety
18 and effectiveness included in the brand manufacturer’s original NDA, and must show
19 that the generic drug contains the same active ingredient(s), dosage form, route of
20 administration, and strength as the brand drug, and is absorbed at the same rate and to
21 the same extent as the brand drug—that is, that the generic drug is pharmaceutically
22 equivalent and bioequivalent (together, “therapeutically equivalent”) to the brand drug.
23 *See generally* 21 U.S.C. 21 U.S.C. § 355(j) *et seq.* Thus, a therapeutically equivalent
24 generic drug is identical to a brand name drug in dosage, form, safety, strength, route of
25 administration, and intended use.

26 36. Generic drugs that are therapeutically equivalent to their brand
27 counterparts are given an “AB” rating by the FDA, allowing their substitution for the
28 brand drug when a patient presents a prescription for the brand product.

37. Congress enacted the Hatch-Waxman Amendments to expedite the entry of generic competitors, thereby reducing healthcare expenses nationwide. As a result, generic drugs became an increasingly large part of prescription drug revenues, and a growing threat to brand-name drug profits. In 1984, prescription drug revenue for brand and generic drugs totaled \$21.6 billion, with generic drugs accounting for 18.6% of total prescriptions. By 2013, total prescription drug revenue had climbed to more than \$329.2 billion, with generic drugs accounting for 86% of prescriptions. *See* IMS Institute for Healthcare Informatics, *Medicine and Shifting Costs of Healthcare* 30, 51 (2014).

2. Paragraph IV Certifications

38. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications: that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification"); that the patent for the brand drug has expired (a "Paragraph II certification"); that the patent for the brand drug will expire on a particular date, and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

39. When a generic manufacturer files a Paragraph IV certification it must promptly provide notice to the brand manufacturer. The filing of an ANDA with a Paragraph IV certification gives rise to a cause of action for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months from the notification date, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval,"

1 but cannot authorize the generic manufacturer to go to market with its product. The
2 FDA may grant an ANDA tentative approval when it determines that the ANDA would
3 otherwise be ready for final approval, but for the 30-month stay. As a practical matter,
4 the initiation of a patent infringement action provides the brand manufacturer with the
5 equivalent of an automatic 30-month injunction that prevents the generic manufacturer
6 from releasing a competing generic product, regardless of the merits of the infringement
7 action.

8 **B. Generic Versions of Brand Drugs Take Significant Sales from the**
9 **Corresponding Brand Versions**

10 40. The only material difference between generic drugs and branded drugs is
11 their price: when there is a single generic drug competitor during the first 180 days of
12 generic marketing, the generic drugs cost on average 82% as much as their branded drug
13 counterparts did before generic entry. The discount typically becomes deeper as time
14 goes on as additional generic drug manufacturers enter the market for a given branded
15 drug. One year after generic entry, generic drugs cost, on average, 15% as much as the
16 branded drug cost prior to generic entry. The Federal Trade Commission (FTC)
17 estimates that about one year after market entry, a generic drug takes over 90% of the
18 branded drug's unit sales.² The launch of a generic drug thus usually brings huge cost
19 savings for all drug purchasers. In fact, "[a]ccording to the Congressional Budget Office,
20 generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies.
21 Even more billions are saved when hospitals use generics."

22 41. In every state, pharmacists are permitted (and, in some states, required) to
23 substitute a generically-equivalent product for the brand product prescribed, unless the
24 doctor has indicated that the prescription for the brand product must be "dispensed as
25 written." Because of the price differentials, and other institutional features of the
26

27
28 ² FTC Staff, Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions
(2010).

1 pharmaceutical industry, generic versions are liberally and substantially substituted by
2 pharmacists when an end-payor presents a prescription for the brand counterpart.

3 42. There is an incentive to choose the less expensive generic drug equivalent in
4 every link in the prescription drug chain. As a result of federal reimbursement rules and
5 the industry pricing structure, pharmacies typically earn a higher markup on generic
6 drugs than on branded drugs. Private health insurers similarly offer direct incentives to
7 pharmacies to substitute cheaper generic drugs for more expensive branded drugs.
8 Health insurers are contractually obligated to pay for the bulk of their insureds'
9 prescriptions, whether filled with branded drugs or generic drugs, so they offer lower co-
10 pays for generic drugs to encourage their use.

11 43. Generic competition enables all members of the proposed Class to: (a)
12 purchase generic versions of the drug at substantially lower prices; and/or (b) purchase
13 the brand drug at a reduced price.

14 44. Until a generic manufacturer enters the market, however, there is no
15 bioequivalent generic drug to substitute for and otherwise compete with the brand drug.
16 The brand manufacturer can therefore continue to charge supracompetitive prices
17 profitably without losing a substantial portion of its brand sales. Consequently, brand
18 manufacturers have a strong incentive to delay generic competition. For Merck, that
19 incentive was particularly strong: in 2010, U.S. sales of Zetia brought in approximately
20 \$1.3 billion.

21 **C. Brand Manufacturers Make No-Authorized Generic Promises to Delay**
22 **Generic Competition**

23 45. Generic companies generally make about 80% of their total income on a
24 generic product when that product is the sole generic equivalent of the corresponding
25 branded drug.

26 46. To avoid losing substantial market share (and revenue) when the first
27 generic enters the market, brand manufacturers will often launch their own "authorized
28 generic" version of the branded drug. An authorized generic is the branded drug that is

1 sold as a generic product under the brand product's original NDA. Because the brand
2 manufacturer already has approval to sell its branded drug, it does not need to file an
3 ANDA, or obtain any additional approvals, to market an identical generic version of its
4 own brand drug. ANDA filers cannot prevent the brand manufacturer from launching an
5 authorized generic version of the brand drug.

6 47. For the brand manufacturer, an authorized generic provides a low cost, low
7 risk means to regain some of the revenue lost from the termination of brand exclusivity.
8 For a generic manufacturer, however, the launch of a brand manufacturer's authorized
9 generic has a substantial negative impact on revenue. If a brand manufacturer launches
10 an authorized generic when there is only one generic product on the market, it typically
11 prices its authorized generic competitively as against that non-authorized generic and
12 thus captures approximately 50% of total generic sales during that period.

13 48. To prevent that loss of revenue from an authorized generic launch, a
14 generic manufacturer that would otherwise have the only generic product on the market
15 may be willing to delay its market entry in return for the brand company's agreement not
16 to launch a competing authorized generic for a period of time after the generic
17 manufacturer begins to market its product, as Merck and Glenmark agreed to do here. A
18 brand manufacturer's promise not to launch an authorized generic is a very valuable
19 payment to a generic company with first-filer status. The promise doubles the generic
20 entrant's sales volume during that time, and because it removes a source of price
21 competition from the market, it more than doubles the generic entrant's revenues and
22 profits. Correspondingly, a brand's promise not to launch an authorized generic
23 represents a substantial sacrifice of the revenues and profits that the authorized generic
24 would otherwise have created for the brand. Those revenues and profits are instead
25 ceded, by way of the no-authorized generic promise, to the generic company.
26
27
28

1 49. In a report by the FTC issued at the request of Congress in 2011 entitled
2 Authorized Generic Drugs: Short-Term Effects and Long-Term Impact,³ the FTC
3 concluded that no-authorized generic agreements have become a common form of
4 payment from brands to generics to induce delayed generic entry. The FTC analyzed
5 documents and empirical data covering more than 100 companies and found that the
6 presence of authorized generic competition can reduce a generic's revenues by 40-52%
7 during its 180 days of generic exclusivity. *Id.* at iii. The FTC found that a generic
8 company makes significantly less money when it competes with an authorized generic
9 because (1) the authorized generic takes a significant share of generic sales away from the
10 first-filer (around 40-50%), and (2) prices drop when the first generic must compete with
11 an authorized generic. A no-authorized generic promise prevents that reduction in
12 revenue. The FTC noted that "there is strong evidence that agreements not to compete
13 with an authorized generic have become a way for brand-name companies to compensate
14 generic competitors for delaying entry. These agreements can be part of 'pay-for-delay'
15 patent settlements, which have long concerned the Commission."

16 50. For an initial generic manufacturer (like Glenmark) of a branded product
17 (like Zetia), the difference between selling the only generic product and competing
18 against an authorized generic for the first months of generic marketing can amount to a
19 payment of hundreds of millions of dollars. These economic realities are well known in
20 the pharmaceutical industry, and the FTC's report on authorized generic cites
21 numerous documents from industry participants confirming the financial impact of an
22 authorized generic.

23 51. A no-authorized generic promise, like the one Merck made in exchange for
24 Glenmark's promise to delay introduction of generic Zetia, thus allows horizontal
25 competitors to benefit from an agreement not to compete and denies end-payor
26

27 ³Available at [https://www.ftc.gov/sites/default/files/documents/reports/authorized-](https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf)
28 [generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-](https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf)
[commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-](https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf)
[federal-trade-commission.pdf](https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf) (last accessed March 21, 2018).

1 purchasers the significantly reduced prices that should flow to them from increased
2 competition.

3 **VI. FACTUAL ALLEGATIONS**

4 **A. Background**

5 52. Zetia is prescribed to treat patients with high cholesterol
6 (hypercholesterolemia), which can lead to atherosclerosis, heart attack, or stroke.
7 Cholesterol in humans comes from two primary sources: dietary intake and production
8 in the liver. Zetia operates by inhibiting the absorption of cholesterol in the small
9 intestine, specifically by inhibiting the enzyme Acyl-CoA cholesterol acyltransferase
10 (ACAT), which facilitates the body's absorption of cholesterol in the intestines. ACAT
11 inhibitors impede the absorption of cholesterol, which in turn reduces serum cholesterol
12 (i.e. cholesterol in the bloodstream).

13 53. Statins are another widely used class of cholesterol medications. Unlike
14 ACAT inhibitors like Zetia, statins operate by inhibiting the body's production of
15 cholesterol by the liver. Many patients cannot take statins because they cause serious
16 side effects. Because Zetia does not cause these side effects, many patients who cannot
17 take statins take Zetia for high cholesterol. Statins are not AB-rated to Zetia, however,
18 and cannot be automatically substituted for Zetia by pharmacists. Statins also do not
19 exhibit substantial cross-price elasticity of demand with respect to Zetia, and thus are not
20 economic substitutes for, nor reasonably interchangeable with, Zetia.

21 54. In the 1990s, Merck scientists attempted to discover new ACAT inhibitors.
22 Scientists working in Schering's New Jersey facilities began developing promising
23 azetidinone compounds that, hopefully, would be useful in reducing cholesterol levels in
24 humans. Those scientists included Stuart B. Rosenblum, Sundeep Dugar, Duane A.
25 Burnett, John W. Clader, and Brian McKittrick.

26 55. These scientists identified a lead compound, SCH48461, and inherent
27 metabolites and metabolite-like analogues of that compound, including SCH58235 or
28 "ezetimibe." (Ezetimibe would eventually become the active ingredient in Zetia).

1 56. Upon discovering these and other useful compounds (and their
2 metabolites), and recognizing their potential to be developed into lucrative prescription
3 drugs down the road, Merck set out to obtain broad patent protection.

4 57. Merck knew that publishing journal articles about its research and
5 development could potentially undermine its ability to patent its inventions. So, while its
6 discoveries occurred in the early 1990s, its scientists did not publish their discoveries
7 until after the first patent application was filed and, in some instances, only wrote about
8 the development process over a decade later.

9 **B. 1993-1998: Merck Applies for, and Obtains, the Original Azetidinone**
10 **Patents (the '365, '115, and '966 Patents)**

11 58. Beginning in 1993, Merck filed a series of related U.S. patent applications
12 addressing hydroxyl-substituted azetidinone compounds useful as hypocholesteremic
13 agents.⁴ Three issued as patents; one of these then *reissued* twice.

14 59. The “azetidinone patents” include U.S. Patent No. 5,631,365 (“the '365
15 patent”), U.S. Patent No. 5,767,115 (“the '115 patent”), U.S. Patent No. 5,846,966
16 (“the '966 patent”), the RE'721 reissue patent, and the RE'461 reissue patent.

17 60. On May 20, 1997, the '593 application—Merck’s second azetidinone patent
18 application—issued as U.S. Patent No. 5,631,365. The '365 patent was the first-issued
19 Merck azetidinone patent. The inventors of the '365 patent are Drs. Rosenblum, Dugar,
20 Burnett, Clader, and McKittrick. All worked for Schering in New Jersey. The '365
21 patent was originally assigned to Schering Corporation of Kenilworth, N.J. In 2012,
22 Merck Sharp & Dohme became the assignee of the '365 patent by means of a conveyance
23 from Schering Corporation.

24 61. The '365 patent states that “the present invention relates to hydroxyl-
25 substituted azetidinones useful as hypocholesterolemic agents in the treatment and
26 prevention of atherosclerosis. . . . [T]he invention also related to a process for preparing
27

28 ⁴ All of the patent applications and communications with the PTO described herein were
done by Schering Corporation and its agents, unless otherwise noted.

hydroxyl-substituted azetidinones.” It observes that “A few azetidinones have been reported as being useful in lowering cholesterol and/or in inhibiting the formation of cholesterol-containing lesions in mammalian arterial walls,” citing U.S. Patent No. 4,983,594; Ran, *Indian J. Chem.* (1990); European Patent Publication No. 264,231; European Patent No. 199,630; and European Patent Application No. 337,549.

62. The summary of the invention describes hypocholesterolemic compounds of formula I or a pharmaceutically acceptable salt of those compounds. It also states that the invention “relates to” all of the following:

- “[A] method of lowering the serum cholesterol level in a mammal in need of such treatment comprising administering an effective amount of a compound of formula I;”
- “[A] pharmaceutical composition comprising a serum cholesterol lowering effective amount of a compounds of formula I in a pharmaceutically acceptable carrier;”
- “[T]he use of a hydroxyl-substituted azetidinone cholesterol absorption inhibitor of formula I for combined use with cholesterol biosynthesis inhibitors [e.g., statins] ... to treat or prevent atherosclerosis or to reduce plasma cholesterol levels;” and
- “[A] process for preparing certain compounds of formula I comprising [five specific steps].”

63. The ’365 patent expired on May 20, 2014.

64. On June 16, 1998, the ’751 application issued as U.S. Patent No. 5,767,115. The ’115 patent had nine claims. Claims 1-7 claim compounds, claim 8 claims a pharmaceutical composition for the treatment or prevention of atherosclerosis (or for the reduction of plasma cholesterol levels), and claim 9 covers a method of treating or preventing atherosclerosis (or reducing plasma cholesterol levels) comprising administering to a mammal in need of such treatment an effective amount of a compound of claim 1.

65. Ezetimibe (the active ingredient in Zetia) is within the scope of claims 1-3, 5, and 7 of the '115 patent. Ezetimibe is designated "6A" and is described in Example 6 at column 31, lines 1-10 of the specification and in claim 7 at column 40, lines 19-21.

66. According to Merck, the '115 patent expired on June 16, 2015.

67. On December 9, 1998, the '825 application issued as U.S. Patent No. 5,846,966.

68. All claims in the '966 patent refer to a hydroxyl-substituted azetidinone used *in combination with* an HMG CoA reductase inhibitor—*i.e.*, a statin. Claim 1 refers to hydroxyl substituted azetidinone compounds used in combination, claims 2-5 refer to compositions of those compounds used in combination, and claim 6 refers to methods of treating or preventing atherosclerosis or reducing plasma cholesterol levels in combination with statins. Claim 8 explicitly refers to simvastatin (the active ingredient in Merck's Zocor) and atorvastatin (Pfizer's Lipitor).

C. 2000: Merck Asks the PTO to Reissue the '115 Patent with New Ezetimibe Claims

69. In early 2000, Merck—including Schering Corporation—was preparing a New Drug Application for the drug product that came to be known as Zetia. Merck closely reviewed the existing patent portfolio, knowing, as all sophisticated pharmaceutical manufacturers do, that the FDA would require them to identify the patents that claim the Zetia product (or a method of using it) by listing them in the Orange Book.

70. On June 15, 2000, Merck filed Reissue Application No. 09/594,996, asking the PTO to reissue the '115 patent. In preliminary remarks, Merck stated that the reissue application was filed "to correct an error concerning the failure to appreciate the full scope of the invention by not including claims of narrower scope directed to one of the most preferred compounds disclosed in the specification," namely, ezetimibe (described as 1-(4-fluoro[phenyl]-3(R)-[3(S)-(4 fluorophenyl)-3-hydroxypropyl])-4(S)-(4-

1 hydroxyphenyl)-2-azetidinone), among other claims. On May 28, 2002, the Patent
2 Office re-issued the patent as U.S. Patent No. RE37,721.

3 **D. 2001-2002: Merck Obtains Approval for Zetia, the RE'721 Patent, and**
4 **a Corresponding 16-month Patent Term Extension**

5 **1. 2001: The FDA Approves Merck's NDA for Zetia**

6 71. On December 27, 2001, while the application for reissue was pending,
7 Merck submitted NDA 21445 seeking FDA approval to market ezetimibe tablets in the
8 United States under the brand name Zetia for the treatment of hypercholesterolemia.

9 72. The FDA's review of Zetia took about ten months. Merck later sought and
10 obtained a patent term extension for the period encompassed by this regulatory review
11 (discussed below).

12 73. On October 25, 2002, the FDA approved the Zetia NDA and granted it a
13 five-year New Chemical Entity exclusivity. Merck launched Zetia later that month. Zetia
14 quickly became a steady source of profits for Merck, with annual U.S. sales of about \$1
15 billion in 2010, \$1.4 billion in 2014, and \$2.6 billion by 2016.

16 74. On December 12, 2002, Merck—via James R. Nelson of Schering—
17 requested an extension of the patent term of the RE'721 patent based on the duration of
18 the FDA's review of the Zetia NDA. Merck asked that an additional 497 days of patent
19 term be added. On January 17, 2006, the Patent Office extended the RE'721 patent
20 through October 25, 2016.

21 **E. 2006: Merck Obtains Its First "Sterol Non-Absorption" Patent (the**
22 **'106 Patent)**

23 75. After Merck filed its NDA, but before it was approved, Merck sought to
24 extend its patent protection for Zetia. Merck filed a series of patent applications relating
25 to compounds that inhibit sterol absorption and methods for treating specific conditions
26 with those compounds. Two issued as patents (the '106 patent and the '058 patent) (or
27 the "the sterol non-absorption" applications and patents).
28

1 76. The sterol non-absorption applications did not claim priority to, or derive
2 from, the azetidinone applications. Nor did they share any inventors.

3 77. On April 18, 2006, Merck's Application No. 10/136,968⁵ issued as U.S.
4 Patent No. 7,030,106. According to Merck, the '106 patent originally was set to expire
5 on January 25, 2022 but, with a pediatric extension, is now set to expire on July 25, 2022.

6 78. The '106 patent specification states, "the present invention relates to
7 therapeutic combinations of peroxisome proliferator-activated receptor (PPAR)
8 activator(s) **and** sterol absorption inhibitor(s) for treating vascular conditions (including
9 atherosclerosis)." (emphasis added).

10 79. But neither of the claims in the '106 patent refers to combination use. Both
11 claim pharmaceutical compositions of ezetimibe that were earlier disclosed in the
12 RE'721 patent.⁶ Given this and other earlier disclosures, the '106 patent is, and clearly
13 was at the time of its issuance, invalid as obvious and/or for obviousness-type double
14 patenting.

15 80. By this time, Merck/Schering had listed in the Orange Book the RE'721
16 azetidinone patent, the '966 combination-with-statins patent, and the '106 sterol non-
17 absorption patent. The '365 process patent was not listed in the Orange Book, likely
18

19 _____
20 ⁵ On January 25, 2002, Merck filed Utility Application No. 10/057,323. The '323
21 application claimed priority to two provisional applications, filed in January 26, 2001,
22 and September 21, 2001, respectively. It did not claim priority to, nor was it related to,
23 the azetidinone patents described above. On May 1, 2002, Merck filed Application No.
10/136,968 as a divisional of the '323 application. The primary examiner was San-Ming
Hui. The '323 and '968 applications purported to address compounds and compositions
that inhibited sterol absorption.

24 ⁶ The compound represented in Formula II of claims 1 and 2 of the '106 patent is
25 ezetimibe. The table in claims 1 and 2 describing the composition lists lactose
26 monohydrate (a sugar); microcrystalline cellulose (a starch); povidone (a disintegrant);
27 crosscarmellose sodium (a dissolving agent); sodium lauryl sulfate (a foaming agent);
28 and magnesium stearate (a release agent). All are conventional excipients and additives.
The RE'721 specification explicitly refers to compositions made using conventional
excipients and additives and conventional techniques, including "non-toxic compatible
fillers, binders, disintegrants, buffers, preservatives, antioxidants, lubricants, flavorings,
thickeners, coloring agents, emulsifiers and the like."

1 because process patents—unlike product or method of use patents—are not eligible for
2 listing.

3 **F. 2006: Glenmark Files the First ANDA for Generic Zetia**

4 81. On October 25, 2006, generic drug manufacturer Glenmark filed ANDA 78-
5 560, seeking FDA approval to market an AB-rated generic version of Zetia.

6 82. Merck's new chemical entity exclusivity expired on October 25, 2007, one
7 year from the date Glenmark filed. Glenmark could not come to market until after that
8 exclusivity expired.

9 83. Glenmark's ANDA included a paragraph IV certification to all of the
10 patents then listed in the Orange Book: the RE'721 azetidinone patent, the '966
11 combination-with-statins patent, and the '106 sterol non-absorption patent.⁷

12 84. On or about February 9, 2007, Glenmark notified Merck of its ANDA filing
13 and provided a detailed account of why the patents were invalid, unenforceable, and not
14 infringed by Glenmark's ANDA product ("Glenmark's paragraph IV letter").

15 85. On March 22, 2007, Merck⁸ sued Glenmark in the District of New Jersey.
16 Merck alleged that Glenmark's ANDA infringed the RE'721 patent (only). Merck did
17 not sue Glenmark, in this suit or any other, for infringing the two other Orange Book
18 listed patents, the '966 or the '106 patents.

19 86. Under the Hatch-Waxman Act, Merck's filing of the RE'721 lawsuit—
20 regardless of its merits—triggered a 30-month stay, running from the date Glenmark
21 notified Merck of its paragraph IV letter. This stay prevented the FDA from granting
22 final approval of Glenmark's ANDA until the earlier of (i) the expiration of the thirty-
23

24
25
26 ⁷ Because the '365 process patent was not listed in the Orange Book, Glenmark did not
need to certify to it in its ANDA.

27 ⁸ In this litigation, plaintiffs Schering Corporation and MSP Singapore Company LLC
28 referred to themselves collectively as "Schering." They are referred to as "Merck" in
this complaint.

1 month stay, or (ii) entry of a final judgment that the RE'721 patent was invalid,
 2 unenforceable, and/or not infringed.⁹

3 87. Glenmark represented in a pleading early on that “[t]he amount at issue in
 4 this case is at least \$1 billion, representing the anticipated sales by Glenmark of its
 5 generic product (and the corresponding loss of sales by [Merck]).”

6 88. On May 23, 2007, Glenmark answered, listed its affirmative defenses, and
 7 counterclaimed. Glenmark sought a declaratory judgment that the RE'721 patent was
 8 invalid and/or unenforceable. Glenmark asserted that the RE'721 patent was invalid for
 9 double patenting, anticipation, obviousness, a lack of enablement, and inventorship
 10 issues. Glenmark also asserted that the RE'721 patent was unenforceable due to
 11 inequitable conduct and that Merck was estopped or precluded from asserting
 12 infringement by reasons of actions taken and statements made to the PTO during
 13 prosecution of the application(s) that led to the RE'721 patent.¹⁰ Glenmark refined these
 14 arguments as the litigation progressed.

15 **G. Spring 2009: Glenmark Receives Tentative Approval, and Merck**
 16 **Receives New Regulatory Exclusivities**

17 89. On April 24, 2009, the FDA gave tentative approval to Glenmark's Zetia
 18 ANDA. It did so within the 30-months allotted by statute, ensuring Glenmark's first-filer
 19 180-day exclusivity. At the time Glenmark received tentative approval, the 30-month
 20 stay prevented Glenmark from launching.

21 90. In 2009, the FDA listed a new exclusivity in the Orange Book—for adding
 22 pediatric information to the label—which expired on June 5, 2011. The FDA also added
 23

24 ⁹ Thirty months from the date Glenmark sent its paragraph IV certification is August 9,
 25 2009. At one point during the litigation, Merck asserted that the 30-month stay expired
 26 on October 25, 2010. Plaintiff alleges here that generics would have entered as early as
 27 December 6, 2011, so the day on which the stay expired—under either interpretation—is
 28 before alleged generic entry and therefore irrelevant to Plaintiff's claims.

¹⁰ In Glenmark's first amended answer and counterclaim, filed on March 10, 2008, it
 added a claim asserting that the 497-day patent term extension Merck received for the
 RE'721 patent was invalid.

1 pediatric exclusivities to all listed patents and exclusivities, which expired on December
2 6, 2011.

3 **H. Summer 2009: Glenmark Seeks Partial Summary Judgment on Two**
4 **Discrete Legal Issues**

5 91. In separate motions for partial summary judgment in July of 2009,
6 Glenmark raised two discrete legal issues as to which it did not believe there to be any
7 disputed issues of facts. At that time, trial was scheduled for May of 2010.

8 92. Motion re Reissue Error: Glenmark argued that the RE'721 patent was
9 invalid for Merck's failure to identify an error of the type that may be properly corrected
10 in reissue. Glenmark argued that the '115 patent was not, as issued, wholly or partly
11 invalid, and that therefore it could not be properly reissued under 35 U.S.C. § 251.

12 93. Motion re Double-Patenting: Glenmark argued that 12 of the 13 claims in
13 the RE'721 patent were invalid by reason of obviousness-type double patenting, in light
14 of Merck's earlier issued '365 patent.

15 94. On November 3, 2009, while the Glenmark summary judgment motions
16 were pending, Merck's Application No. 10/998,40055 issued as U.S. Patent No.
17 7,612,058, Merck's second sterol non-absorption patent.

18 95. On April 19, 2010, the court granted Glenmark's motion on invalidity,
19 agreeing with Glenmark that reissuance of the '115 patent had been improper because
20 Merck had failed to identify the kind of purported error that can be corrected in reissue.
21 This functionally threw out claims 10-13, which claimed ezetimibe expressly and had
22 been added in reissue. Merck moved for reconsideration of this order on April 30, 2010.

23 96. On the same day, the court denied Glenmark's second motion for partial
24 summary judgment (obviousness double patenting), concluding that disputed issues of
25 fact as to whether, at the time of the '365 patent, alternative processes for making the
26 claimed azetidinone compounds existed.

I. Two Days Before Trial, Merck and Glenmark Agree to Settle with a Large Reverse Payment

97. Trial was scheduled to begin on May 12, 2010. At issue were Glenmark's affirmative defenses and counterclaims, including its assertion that claims 1 through 9 were unenforceable because of Merck's intentional failure to disclose to the PTO either (1) compounds claimed in the RE'721 were naturally occurring metabolites of SCH46481 (and therefore inherently anticipated by earlier disclosures) or (2) the disqualifying prior art publications by Merck's own scientists that had been hidden from the PTO.

98. On May 10, 2010, two days before the scheduled start of trial, Merck and Glenmark entered into an agreement that settled the patent infringement lawsuit but, as later events would show, also included unlawful "pay for delay" or reverse payment terms.

99. Merck and Glenmark agreed to entry of a consent judgment.

100. The proceedings on entry of the consent judgment revealed that the parties had agreed that, subject to certain unrevealed caveats, Glenmark would not enter the market with its generic Zetia product until December 12, 2016.

101. Although the consent judgment referenced the settlement agreement, it was not docketed in the court record. The parties did not publicly reveal any of the remaining terms of that agreement at the time of the settlement. Nor have the other terms of that agreement ever been made public.

102. Certain terms of the agreement were revealed only by later events. Upon information and belief, as a quid pro quo for Glenmark's agreement to drop its patent challenge and delay market entry for over five years, Merck promised not to launch a competing authorized generic version of Zetia during Glenmark's eventual 180-day exclusivity period (the "no-AG agreement"). The existence of a no-AG agreement is inferred from the following facts:

a. First, Merck previously admitted that marketing an authorized generic is often in its economic interest. For example, speaking about another

1 blockbuster drug, Fosamax, a Merck executive acknowledged that Merck's "authorized
2 generic strategy" will "maximize the value of the franchise" after entry by generic
3 competitors.

4 b. Second, Merck had a well-established history of launching authorized
5 generics in the face of generic competition. Other branded drugs for which Merck or
6 Schering has launched authorized generic versions include Blocadren, Clinoril, Cozaar,
7 Diprolene, Lotrisone, Nasonex, Singulair (Oral Granules), Temodar, Blocadren, K-Dur
8 10, K-Dur 20, and Lotrimin AF.

9 c. Third, Zetia was a blockbuster drug, with sales in the billions at the
10 time that a generic eventually launched in 2016. Absent Glenmark's reciprocal
11 agreement to delay entering the market, launching an authorized generic would have
12 been in Merck's financial interest.

13 d. Fourth, when Glenmark launched its generic on December 12, 2016,
14 it issued a press release describing its generic Zetia as "the first and only generic
15 version" of Zetia in the United States.

16 e. Fifth, when Glenmark eventually did launch generic Zetia in late
17 2016, Merck did not launch an authorized generic during Glenmark's 180-day ANDA-
18 exclusivity period. That decision is strong evidence that Merck agreed with Glenmark
19 not to launch such a product. During Glenmark's first 180 days on the market, Merck
20 stood to earn hundreds of millions of dollars from an AG launch.

21 f. Sixth, Glenmark reported to its shareholders in May 2017 that, before
22 launching the product, it had expected to take well more than 58% of the combined brand
23 and generic Zetia sales that it had in fact achieved by then. As noted in detail above, in
24 the absence of a no-AG pact, a reasonable pharmaceutical company would realistically
25 expect to take only about 40% of the market (one half of the standard 80% erosion rate).

26 103. On information and belief, the no-AG agreement was a payment to
27 Glenmark from Merck worth substantially more than Glenmark could have earned if it
28 had come to market with generic Zetia in 2011. Glenmark could not have obtained a no-

1 AG agreement even had it won the patent infringement litigation. By delaying generic
2 entry for more than five years, and thereby obtaining the no-AG agreement from Merck,
3 Glenmark was ensured six months of exclusive generic sales, free from competition from
4 Merck's authorized generic or any other generic competitors.

5 104. For Merck, the benefits of the no-AG agreement were enormous. While it
6 would forgo six months of profits on an authorized generic, in turn it would enjoy more
7 than five years of monopoly profits selling much more expensive and profitable branded
8 Zetia.

9 105. The value of the reverse payment agreement to Merck and Glenmark can be
10 estimated using the known economics of the pharmaceutical industry.

11 106. Defendants executed the reverse payment agreement in May 2010. That
12 agreement delayed Glenmark's generic entry until December 2016. Absent the reverse
13 payment, generic entry would have occurred much sooner than it did, and as early as
14 December 6, 2011.

15 107. By that time, other than the RE'721 (addressed momentarily), no other
16 impediments existed to the prompt approval and launch of generic Zetia.

17 108. First, Glenmark's ANDA had already received FDA tentative approval. In
18 effect, Glenmark had met all preconditions for final FDA approval other than the 30-
19 month stay.

20 109. Second, no other patents held by Merck would forestall generic entry. The
21 '966 patent had claims only to combination products, but generic Zetia is not a
22 combination product, and Merck never enforced the '966 patent against Glenmark. The
23 '106 and '058 sterol nonabsorption patents were obvious in light of the RE'721
24 disclosures, and Merck never enforced those patents against Glenmark. The '365 patent
25 was limited to the narrow processes set out in that patent, and Merck never enforced the
26 '365 patent against Glenmark.

27 110. Third, no other exclusivity existed after December 5, 2011. The NCE
28 exclusivity expired in 2007. Two other exclusivities—an indication exclusivity I-493 and

1 a pediatric exclusivity M-54—were likely capable of being carved out of any generic
2 label, and in any event had expired by December 5, 2011.

3 111. As to the RE'721 patent, in the absence of the reverse payment, generic
4 entry would have occurred much sooner than it did. Absent the reverse payment,
5 reasonable, economically rational companies in the position of Glenmark and Merck may
6 still have settled the litigation, but without a reverse payment, and with an earlier agreed
7 entry date. Alternatively, absent the reverse payment, Glenmark would have won the
8 trial scheduled to start in May 2010. A finder of fact would have concluded that Merck
9 failed to prove that Glenmark infringed a valid patent. A reasonable, economically
10 rational company in the position of Glenmark would have launched generic Zetia soon
11 after a district court ruling in its favor and the expiration of any other, lawful exclusivity.

12 112. Without the large and unjustified payment, several additional generics
13 would have come to market after Glenmark's 180-day exclusivity ended—as early as
14 June 6, 2012, and in any event much earlier than June 12, 2017. Merck's last regulatory
15 exclusivity ran on December 6, 2011. By then, Glenmark would have resolved the
16 RE'721 infringement claims by either winning at trial or settling on competitive terms
17 (without a reverse payment), or launching at risk.

18 113. In the absence of the large and unjustified payment, Merck would have
19 launched its authorized generic version of Zetia at or around the same time that
20 Glenmark launched its generic.

21 **J. The Value of the No-AG Agreement**

22 114. Merck would have lost about 80% of its branded sales upon generic entry.
23 But without generic entry, it kept all those sales until the end of 2016.

24 115. Because Glenmark was the first ANDA filer, its agreement not to launch
25 generic Zetia until December 2016 created a competition bottleneck preventing other
26 generic companies from marketing a generic Zetia product until 180 days after Glenmark
27 launched its generic product.
28

1 116. According to public sources, Merck's revenues from sales of Zetia were
2 approximately \$1.3 billion in 2011, \$1.4 billion in 2012, \$1.7 billion in 2013, \$2 billion in
3 2014, \$2.2 billion in 2015, and \$2.6 billion in 2016, for a total of approximately \$11.2
4 billion (not including the second half of 2010). By inducing Glenmark to delay its entry
5 into the Zetia market, the no-AG provision likely resulted in billions of additional sales
6 that Merck would not have enjoyed absent the agreement.

7 117. The no-AG agreement likely resulted in hundreds of millions of additional
8 sales for Glenmark. Without competition from Merck's authorized generic, Glenmark
9 could expect to capture 80% of the sales of the branded product in 2016, and likely would
10 have priced its generic product at about 90% of the brand's price. As a result, during its
11 six-month exclusivity period in 2016, without competition from Merck's authorized
12 generic, Glenmark realized about \$936 million in generic sales (\$2.6 billion times 0.5
13 [1/2 year] times 0.8 [generic penetration] times 0.9 [generic price]). Glenmark's sales
14 would have been a fraction of \$936 million if it had entered the market earlier (before the
15 Zetia market had grown to 2016 levels) and faced competition from an authorized
16 generic.

17 **K. 2016: Glenmark Launches a Generic Form of Zetia; Merck Does Not**

18 118. Glenmark's ANDA 78-560 received final FDA approval on June 26, 2015.
19 In its final approval letter, the FDA reconfirmed that Glenmark was entitled to 180-days
20 of market exclusivity upon launch.

21 119. On December 12, 2016, Glenmark launched its generic Zetia. The same day
22 it issued a press release announcing that its product was "the first and only generic
23 version" of Zetia in the United States. Glenmark launched its generic product in
24 partnership with Par Pharmaceuticals, an operating company of Endo International PLC.

25 120. From December 12, 2016, through June 12, 2017, Glenmark's product was
26 the only generic version of Zetia sold in the U.S. market.
27
28

121. Merck refrained from launching an authorized generic version of Zetia during Glenmark's 180-day exclusivity period. It did so pursuant to the no-AG pact in the parties' unlawful agreement.¹¹

L. 2017: 180 days later, Five More Generics Launch

122. On or about June 12, 2017, the FDA approved ANDAs for generic Zetia previously filed by seven competitor companies: Teva (ANDA 78-724), Sandoz (ANDA 203-931), Amneal (ANDA 208803), Apotex (ANDA 208332), Ohm Laboratories (ANDA 207311), Zydus (ANDA 204331), and Watson Laboratories (ANDA 200831).

123. Five of these manufacturers—Teva, Sandoz, Amneal, Apotex, and Ohm Laboratories—launched a generic Zetia product in June 2017, shortly after receiving FDA approval. Zydus launched its generic Zetia product in August 2017. (Watson Laboratories had sold its generic drug business to Teva before June 2017 and so did not launch a generic Zetia product.)

124. An eighth ANDA, filed by Aurobindo (ANDA 209838), was approved in August 2017. Aurobindo launched its generic product the same month. An additional ANDA, filed by Alkem Laboratories (ANDA 209234), was approved in December 2017.

125. The average retail price of ezetimibe tablets dropped from \$10 per pill before Glenmark's launch, to less than \$0.33 per pill as of December 1, 2017, a 97% decrease.

126. Absent the no-AG promise, Merck would have launched an authorized generic during Glenmark's 180-day exclusivity period, taking approximately 50% of

¹¹ Merck did not launch an authorized generic at the end of Glenmark's 180-day exclusivity in June 2017. But the economics for Merck **after** Glenmark's 180-day exclusivity were radically different than the economics for Merck would have been (absent the unlawful no-AG pact) **during** that exclusivity. After the exclusivity, Merck's authorized generic would have been one of at least seven generics on the market, competing for a margin driven down to near marginal cost. During Glenmark's exclusivity, as noted in detail above, a Merck authorized generic would have been one of only two generics on the market, taking at least half the sales at margins that would have yielded more than a hundred million dollars in profits.

1 Glenmark's generic sales and substantially lowering the price that drug purchasers paid
2 for generic Zetia. Absent the no-AG promise, Glenmark would not have agreed to delay
3 its launch until December 12, 2016, and instead would have entered the market much
4 sooner than it did, as early as December 6, 2011. Additional generics would have entered
5 the market six months later and further driven down prices.

6 127. The settlement with Glenmark enabled Merck to continue to receive
7 monopoly profits until December 12, 2016 and enabled Glenmark to control the generic
8 market for 180 days thereafter, with Glenmark sharing in the monopoly profits that the
9 reciprocal non-competition pact made possible. The reverse payment agreement not
10 only delayed Glenmark's own entry into the market, it also created a bottleneck that
11 blocked all other would-be generic Zetia competitors by postponing the start (and thus
12 also the conclusion) of Glenmark's 180-day first-filer exclusivity period. Shortly after
13 Glenmark's 180-day exclusivity period expired, seven other companies launched their
14 generic Zetia products. Absent Glenmark's unlawful agreement to delay its entry until
15 December 12, 2016, these or other generic manufacturers would have filed their ANDA
16 applications earlier and would have been ready, willing, and able to enter the market on
17 whatever earlier date Glenmark's 180-day exclusivity expired.

18 128. The Merck-Glenmark agreement was collusive and intended to maintain a
19 monopoly and allocate the market.

20 **M. The No-AG Promise Was a Large Reverse Payment**

21 129. The no-AG payment to Glenmark was large, estimated to be worth more
22 than \$800 million. It far exceeded any estimate of the litigation expenses Merck saved by
23 settling the patent case with Glenmark.

24 130. From Merck's perspective, the value of the reverse payment agreement was
25 far greater even than the value to Glenmark, because the years-long delay in generic
26 entry protected Merck's monopoly sales volume and pricing over that time.

27 131. Merck's reverse payment to Glenmark guaranteed two distinct periods of
28 noncompetition: (a) the period before generic competition, wherein Merck and

1 Glenmark allocated 100% of the market to Merck; and (b) the 180-day exclusivity period
2 after Glenmark's entry, wherein Merck and Glenmark allocated 100% of generic sales to
3 Glenmark. So drug purchasers were overcharged twice: before Glenmark's entry, they
4 were forced to pay overcharges for branded Zetia; and during Glenmark's exclusivity
5 period were forced to pay additional overcharges for branded Zetia and generic Zetia.
6 And the unlawful agreement had the additional anticompetitive effect of delaying
7 additional generic competitors.

8 132. The defendants have no procompetitive explanation or justification for the
9 reverse payment agreement.

10 133. If not for the reverse payment settlement agreement between Merck and
11 Glenmark, Glenmark could and would have entered the market much sooner than it did,
12 as early as December 6, 2011, with immediate competition from a Merck authorized
13 generic and full competition with other generics by approximately May 2012. Instead,
14 Glenmark did not release its generic until December 12, 2016, Merck never launched an
15 authorized generic, and generic entry by other manufacturers could not occur until June
16 12, 2017.

17 **VII. INTERSTATE AND INTRASTATE COMMERCE**

18 134. At all material times, Merck manufactured, promoted, distributed, and sold
19 substantial amounts of branded Zetia in a continuous and uninterrupted flow of
20 commerce across state and national lines and throughout the United States. Beginning in
21 December 2016 Glenmark manufactured and Par promoted, distributed, and sold
22 substantial amounts of generic Zetia in a continuous and uninterrupted flow of
23 commerce across state and national lines and throughout the United States.

24 135. At all material times, Defendants transmitted funds as well as contracts,
25 invoices and other forms of business communications and transactions in a continuous
26 and uninterrupted flow of commerce across state and national lines in connection with
27 the sale of Zetia and generic Zetia.
28

136. In furtherance of their efforts to monopolize and restrain competition in the market for branded and generic Zetia, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

137. Defendants' anticompetitive conduct has had substantial intrastate effects in that, among other things, retailers within each state did not have access to less expensive generic Zetia that they could sell to end-payors within each respective state. The delay of generic Zetia has directly impacted and disrupted commerce for end-payors within each state.

138. During the relevant time period, Zetia was shipped into each state and was sold to or paid for by end-payors. Beginning in December 2016, an AB-rated generic version of Zetia was shipped into each state and sold to or paid for by end-payors.

139. Defendants' conduct as alleged herein had substantial effects on intrastate commerce in each state because Zetia was sold to consumers and third-party payors in each state and Defendants entered into an unlawful, anticompetitive Agreement that affected commerce in each state.

VIII. MARKET POWER AND MARKET DEFINITION

140. At all relevant times, Defendants possessed market power over Zetia and its AB-rated generic equivalents because it had the power to maintain Zetia prices at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Zetia and its AB-rated generic equivalents.

141. A small but significant, non-transitory price increase for Zetia by Merck would not have caused a significant loss of sales to drug products other than AB-rated generic versions of Zetia.

142. Zetia does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Zetia.

143. Because of, among other reasons, its use and ability to treat high cholesterol without causing the same side effects as statins, Zetia is differentiated from all products other than AB-rated generic versions of Zetia.

144. Defendants needed to control only Zetia and its AB-rated generic equivalents, and no other products, to profitably maintain the price of Zetia at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Zetia would render Defendants unable to profitably maintain supracompetitive prices for Zetia without losing substantial sales.

145. Defendants possessed, and exercised, the power to exclude and restrict competition to Zetia and its AB-rated generic equivalents.

146. Defendants also sold Zetia and its AB-rated generic equivalents at supracompetitive prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

147. Defendants, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to asserted patent rights and other regulatory protections and high costs of entry.

148. Plaintiff alleges that the relevant market is Zetia and its AB-rated generic equivalents. During the relevant period, Defendants were able to profitably maintain the price of Zetia and its AB-rated generic equivalents well above competitive levels.

149. The relevant geographic market is the United States and its territories.

150. At all relevant times, Defendants' market share in the relevant market was and is 100%, demonstrating substantial market power.

IX. EFFECTS ON COMPETITION, AND DAMAGES

151. Defendants' unlawful Agreement has delayed generic competition, unlawfully enabled Merck to sell branded Zetia without generic competition, and allowed Glenmark to sell generic Zetia without competition from an authorized generic.

152. Were it not for the unlawful Agreement alleged herein, one or more generic Zetia product would have entered the market well before December 12, 2016.

1 153. But for the unlawful Agreement, an authorized generic version of Zetia
2 would have been available on the market simultaneously with the launch of Glenmark's
3 generic or shortly thereafter. End-payors like Plaintiff and other members of the Class
4 would have paid less for Zetia and its AB-rated generic equivalents by (a) substituting
5 purchases of less-expensive AB-rated generic Zetia for their purchases of more-
6 expensive branded Zetia, (b) receiving discounts on their remaining branded Zetia
7 purchases, and (c) purchasing generic Zetia at lower prices sooner. As a result of
8 Defendants' illegal conduct as alleged herein, Plaintiff and other Class members were
9 compelled to pay, and did pay, artificially inflated prices for Zetia.

10 154. Plaintiff and other Class members have purchased substantial amounts of
11 branded Zetia indirectly from Merck and substantial amounts of generic Zetia indirectly
12 from Glenmark. Defendants' unlawful conduct deprived Plaintiff and the Class of the
13 benefits of competition that the antitrust laws were designed to ensure. As a
14 consequence, Plaintiff and other members of the Class have sustained substantial losses
15 and damage to their business and property in the form of overcharges, the exact amount
16 of which will be decided at trial.

17 **X. ANTITRUST IMPACT**

18 155. Supracompetitive prices for pharmaceuticals at a higher level of distribution
19 generally result in higher prices at every level below. This case is no exception.

20 156. Wholesalers and retailers passed on the supracompetitive prices of branded
21 Zetia and AB-rated generic Zetia to Plaintiff and Class members.

22 157. Defendants' anticompetitive conduct enabled them to indirectly raise, fix,
23 and stabilize prices to consumers and third-party payors in excess of the prices
24 Defendants otherwise would have been able to charge absent Defendants'
25 anticompetitive conduct.

26 158. The supracompetitive prices paid by Plaintiff and Class members are
27 traceable to, and the direct, proximate, and foreseeable result of, Defendants'
28 supracompetitive prices.

XI. CONCEALMENT TOLLED THE STATUTE OF LIMITATIONS

159. A cause of action accrued each time Defendants sold Zetia at a supra-competitive price made possible by their anticompetitive conduct. And each sale by Defendants of a product at a supra-competitive constituted another overt act in furtherance of their anticompetitive scheme.

160. In addition, Defendants concealed their unlawful conduct, further tolling the statute of limitations. The reverse payment here—Merck’s agreement not to launch an authorized generic—was not discoverable until after Glenmark launched its generic ezetimibe in December 2016. At that time, Merck did not launch an authorized generic then, or after six months, or ever. Merck and Glenmark had earlier disclosed only cursory information about the existence of the settlement. Plaintiff and members of the Class had no knowledge of Defendants’ unlawful scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence more than four years before the filing of this complaint.

161. That is true because Defendants’ scheme was self-concealing and because Defendants employed deceptive tactics and techniques of secrecy to conceal their contract, combination, conspiracy, and scheme.

162. The defendants and co-conspirators wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from Plaintiff and members of the Class by, among other things:

a. Concealing the fact of Merck’s agreement not to launch a competing authorized generic Zetia product in exchange for Glenmark’s agreement not to market its competing generic product until December 12, 2016;

b. Concealing the fact that the purpose of the no-AG agreement was to provide compensation to Glenmark in connection with the settlement of the patent litigation and the December 2016 entry date for Glenmark’s generic product; and

c. Filing documents with the United States Securities and Exchange Commission that failed to disclose the existence or nature of the payments made.

163. Because the scheme and conspiracy were both self-concealing and affirmatively concealed by Defendants, Plaintiff and members of the Class had no knowledge of the scheme and conspiracy more than four years before the filing of this complaint; nor did they have the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed.

164. Plaintiff and members of the Class also lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred. Reasonable diligence on the part of the plaintiff and members of the class would not have uncovered those facts more than four years before the filing of this complaint.

XII. CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF STATE ANTITRUST LAWS (Asserted against All Defendants)

165. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

166. This claim is pled as to all Defendants.

167. In or about May 2010, and at times prior to the formal execution thereof, Defendants entered into the Agreement. The Agreement is an illegal contract, combination, and conspiracy in restraint of trade under which Glenmark agreed to delay bringing its generic version of Zetia to the market in exchange for Merck's agreement not to introduce an authorized generic version of Zetia during Glenmark's 180-day exclusivity period, the purpose and effect of which were to: (a) delay and/or preclude the entry of less expensive generic versions of Zetia in the United States; (b) delay the introduction of an authorized generic Zetia, which otherwise would have appeared on the market at a significantly earlier time; (c) fix, raise, maintain, or stabilize the prices of Zetia products, even after generic entry; (d) allocate 100% of the United States market for branded Zetia to Merck for up to 79 months; and (e) allocate 100% of the United States market for generic Zetia to Glenmark for up to 6 months.

1 168. Defendants thus implemented the terms of the Agreement and achieved its
2 intended purpose. As a direct and proximate result of Defendants' anticompetitive
3 conduct, as alleged herein, Plaintiff and the Class were harmed as set forth above.

4 169. The Agreement covered a sufficiently substantial percentage of the relevant
5 market to harm competition.

6 170. There was and is no legitimate, non-pretextual, procompetitive justification
7 for the Agreement that outweighs its harmful effect. Even if there were some conceivable
8 justification, the reverse payment was not necessary to achieve that purpose.

9 171. By engaging in the foregoing conduct, Defendants entered a conspiracy and
10 combination in restraint of trade in violation of the following state laws:

11 a. Ala. Code § 6-5-60 with respect to purchases in Alabama by members
12 of the Class and/or purchases by Alabama residents.

13 b. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases in
14 Arizona by members of the Class and/or purchases by Arizona residents.

15 c. Cal. Bus. and Prof. Code §§ 16720, *et seq.*, with respect to purchases
16 in California by members of the Class and/or by purchases by California residents.

17 d. D.C. Code §§ 28-4501, *et seq.*, with respect to purchases in the
18 District of Columbia by members of the Class and/or purchases by District of Columbia
19 residents.

20 e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by
21 members of the Class and/or purchases by Florida residents.

22 f. Haw. Rev. Stat. §§ 480-1, *et seq.*, with respect to purchases in Hawaii
23 by members of the Class and/or purchases by Hawaii residents.

24 g. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchases in Illinois
25 by members of the Class and/or purchases by Illinois residents.

26 h. Iowa Code § 5531 *et seq.*, with respect to purchases in Iowa by
27 members of the Class and/or purchases by Iowa residents.
28

i. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Class and/or purchases by Kansas residents.

j. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class and/or purchases by Massachusetts residents.

k. Me. Rev. Stat. Ann. 10 § 1101, *et seq.*, with respect to purchases in Maine by members of the Class and/or purchases by Maine residents.

l. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases in Michigan by members of the Class and/or purchases by Michigan residents.

m. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases in Minnesota by members of the Class and/or purchases by Minnesota residents.

n. Miss. Code Ann. § 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class and/or purchases by Mississippi residents.

o. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchase in Missouri by members of the Class and/or purchases by Missouri residents.

p. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class and/or purchases by Nebraska residents.

q. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class and/or purchases by Nevada residents.

r. N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to purchases in New Hampshire by members of the Class and/or purchases by New Hampshire residents.

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class and/or purchases by New Mexico residents.

t. New York General Business Law § 340, *et seq.*, with respect to purchases in New York by members of the Class and/or purchases by New York residents.

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class and/or purchases by North Carolina residents.

v. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases in North Dakota by members of the Class and/or purchases by North Dakota residents.

w. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class and/or purchases by Oregon residents.

x. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases in Puerto Rico by members of the Class and/or purchases by Puerto Rico residents.

y. R.I. Gen. Laws §§ 6-36-1 *et seq.*, with respect to purchases in Rhode Island by members of the Class and/or purchases by Rhode Island residents.

z. S.D. Codified Laws Ann. § 37-1-3.1, *et seq.*, with respect to purchases in South Dakota by members of the Class and/or purchases by South Dakota residents.

aa. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class and/or purchases by Tennessee residents.

bb. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Class and/or purchases by Utah residents.

cc. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class and/or purchases by Vermont residents.

dd. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Class and/or purchases by West Virginia residents.

ee. Wis. Stat. § 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class and/or purchases by Wisconsin residents.

172. Plaintiff and Class members have been (and will continue to be) injured in their business or property by reason of Defendants' violations of laws set forth above, in that Plaintiff and Class members (i) were denied the opportunity to purchase lower-priced generic Zetia, and (ii) paid higher prices for branded Zetia than they would have paid but for the unlawful conduct. These injuries are of the type the laws of the above-listed jurisdictions were designed to prevent and flow from that which makes the conduct unlawful.

1 173. Plaintiff and Class members seek damages and multiple damages as
2 permitted by law for their injuries.

3 **CLAIM II: VIOLATION OF STATE CONSUMER PROTECTION**
4 **STATUTES**
5 **(Asserted Against All Defendants)**

6 174. Plaintiff hereby incorporates each preceding and succeeding paragraph as
7 fully set forth herein.

8 175. This claim is pled as to all Defendants.

9 176. By engaging in the foregoing conduct, Defendants have engaged in unfair
10 competition or deceptive acts and practices in violation of the following state laws:

11 a. Alaska Statute § 45.50.471, *et seq.*, with respect to purchases in Alaska
12 by members of the Class and/or purchases by Alaska residents.

13 b. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases in Arkansas
14 by members of the Class and/or purchases by Arkansas residents.

15 c. Ariz. Code §§ 44-1255, *et seq.*, with respect to purchases in Arizona
16 by members of the Class and/or purchases by Arizona residents.

17 d. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases in
18 California by members of the Class and/or purchases by California residents.

19 e. Colo. Rev. Stat. § 6-1-101, *et seq.*, with respect to the purchases in
20 Colorado by members of the Class and/or purchases by Colorado residents.

21 f. 6 Del. Code § 2511, *et seq.*, with respect to purchases in Delaware by
22 members of the Class and/or purchases by Delaware residents.

23 g. D.C. Code §§ 28-3901, *et seq.*, with respect to the purchases in the
24 District of Columbia by members of the Class and/or purchases by District of Columbia
25 residents.

26 h. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by
27 members of the Class and/or purchases by Florida residents.
28

1 i. Ga. Code § 10-1-370, with respect to purchases in Georgia by
2 members of the Class and/or purchases by Georgia residents.

3 j. Haw. Rev. Stat. Ann. § 480-1, *et seq.*, with respect to purchases in
4 Hawaii by members of the Class and/or purchases by Hawaii residents.

5 k. Kan. Stat. §§ 50-623, *et seq.*, with respect to the purchases in Kansas
6 by members of the Class and/or purchases by Kansas residents.

7 l. Idaho Code §§ 48-601, *et seq.*, with respect to the purchases in Idaho
8 by members of the Class and/or purchases by Idaho residents.

9 m. 815 ILCS §§ 505/1, *et seq.*, with respect to the purchases in Illinois by
10 members of the Class and/or purchases by Illinois residents.

11 n. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to the purchases in
12 Maine by members of the Class and/or purchases by Maine residents.

13 o. Mass. Ann. Laws ch. 93A, § 1, *et seq.*, with respect to purchases in
14 Massachusetts by members of the Class and/or purchases by Massachusetts residents.

15 p. Mich. Comp. Laws Ann. §§ 445.903, *et seq.*, with respect to
16 purchases in Michigan by members of the Class and/or purchases by Michigan residents.

17 q. Minn. Stat. §§ 325D.43, *et seq.*, with respect to purchases in
18 Minnesota by members of the Class and/or purchases by Minnesota residents.

19 r. Missouri Stat. §§ 407.010, *et seq.*, with respect to purchases in
20 Missouri by members of the Class and/or purchases by Missouri residents.

21 s. Mont. Code § 30-14-103, *et seq.*, and §30-14-201, *et seq.* with respect
22 to purchases in Montana by members of the Class and/or purchases by Montana
23 residents.

24 t. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases in
25 Nebraska by members of the Class and/or purchases by Nebraska residents.

26 u. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases in
27 Nevada by members of the Class and/or purchases by Nevada residents.
28

1 v. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases in New
2 Hampshire by members of the Class and/or purchases by New Hampshire residents.

3 w. N.J. Stat. § 56-8-1, *et seq.*, with respect to purchases in New Jersey by
4 members of the Class and/or purchases by New Jersey residents.

5 x. N.M. Stat. §§ 57-12-1, *et seq.*, with respect to purchases in New
6 Mexico by members of the Class and/or purchases by New Mexico residents.

7 y. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases in New
8 York by members of the Class and/or purchases by New York residents.

9 z. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases in North
10 Carolina by members of the Class and/or purchases by North Carolina residents.

11 aa. N.D. Cent. Code § 51-15-01, *et seq.*, with respect to purchases in
12 North Dakota by members of the Class and/or purchases by North Dakota residents.

13 bb. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases in Oregon
14 by members of the Class and/or purchases by Oregon residents.

15 cc. 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases in
16 Pennsylvania by members of the Class and/or purchases by Pennsylvania residents.

17 dd. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases in Rhode
18 Island by members of the Class and/or purchases by Rhode Island residents.

19 ee. S.C. Code Ann. § 39-5-10, *et seq.*, with respect to purchases in South
20 Carolina by members of the Class and/or purchases by South Carolina residents.

21 ff. S.D. Code Laws §§ 37-24-1, *et seq.*, with respect to purchases in
22 South Dakota by members of the Class and/or purchases by South Dakota residents.

23 gg. Tenn. Code §§ 47-18-101, *et seq.*, with respect to purchases in
24 Tennessee by members of the Class and/or purchases by Tennessee residents.

25 hh. Utah Code §§13-11-1, *et seq.*, with respect to purchases in Utah by
26 member of the Class and/or purchases by Utah residents.

27 ii. Vt. Stat Ann. 9, § 2451, *et seq.*, with respect to purchases in Vermont
28 by member of the Class and/or purchases by Vermont residents.

jj. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases in Virginia by members of the Class and/or purchases by Virginia residents.

kk. W. Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases in West Virginia by members of the Class and/or purchases by West Virginia residents.

ll. Wisc. Stat. § 100.18, *et seq.*, with respect to purchases in Wisconsin by members of the Class and/or purchases by Wisconsin residents.

**CLAIM III: VIOLATION OF 15 U.S.C. § 1
(On Behalf of SISC and the Nationwide Injunctive Relief Class
pursuant to 15 U.S.C. § 26)**

177. SISC hereby repeats and incorporates by reference each preceding and succeeding paragraphs as though fully set forth herein.

178. Merck and Glenmark violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Zetia and its AB-rated generic equivalents.

179. Par violated 15 U.S.C. § 1 by partnering with Glenmark and furthering the unlawful reverse payment agreement's objective to restrain competition in the market for Zetia and its AB-rated generic equivalents.

180. Indirect purchasers have been injured in their business or property by the violation of 15 U.S.C. § 1. The indirect purchasers' injury consists of having paid higher prices for their ezetimibe requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes the Defendants' conduct unlawful. SISC is the proper entity to bring a case concerning this conduct.

181. From the launch of brand Zetia in 2002 through December 12, 2016, Merck possessed monopoly power in the relevant market—*i.e.*, the market for sales of ezetimibe in the United States. But for Defendants' wrongful conduct, as alleged herein, Merck should have lost its monopoly power in the relevant market as early as December 6, 2011 and in any event well before December 12, 2016.

182. On or about May 10, 2010, Merck and Glenmark entered into a reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Merck paid Glenmark substantial consideration in exchange for Glenmark delaying its launch of a generic version of Zetia. Par knowingly acquiesced to, was consciously committed to, and furthered this illegal contract, combination, and restraint of trade. The purpose and effect of the agreements between Defendants were to: (a) delay generic entry of Zetia in order to lengthen the period in which Merck's brand Zetia could monopolize the market and make supracompetitive profits; (b) keep an authorized generic off the market during Glenmark's 180-day generic exclusivity period, thereby allowing Glenmark and Par to monopolize the generic market for Zetia during that period, and allowing Glenmark and Par to make supracompetitive profits; and (c) raise and maintain the prices that SISC and other members of the Class would pay for Zetia at supracompetitive levels until at least June 12, 2017.

183. There is and was no legitimate, non-pretextual, procompetitive business justification for this reverse payment agreement that outweighs its harmful effect on indirect purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

184. As a direct and proximate result of Merck's, Glenmark's, and Par's anticompetitive conduct, including the reverse payment, SISC was harmed.

185. Plaintiff and the Nationwide Injunctive Relief Class seek equitable and injunctive relief, including disgorgement of profits, under section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and other relief to ensure that the same or similar anticompetitive conduct does not reoccur in the future.

XIII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully requests that the Court:

1 A. Determine that this action may be maintained as a class action pursuant to
2 Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as
3 provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declare the Plaintiff as
4 the representative of the Class;

5 B. Enter joint and several judgments against Defendants and in favor of
6 Plaintiff and the Class;

7 C. Award the Class damages and, where applicable, treble, multiple, punitive,
8 and/or other damages, in an amount to be determined at trial, including interest;

9 D. Grant Plaintiff and the Class equitable relief in the nature of disgorgement,
10 restitution, and the creation of a constructive trust to remedy Defendants' illegal
11 conduct, including:

- 12 i. A judicial determination declaring the rights of Plaintiff and Class
13 members, and the corresponding responsibilities of Defendants;
- 14 ii. A declaration that Defendants are to be financially responsible for the
15 costs and expenses of a Court-approved notice program by mail,
16 broadcast media, and publication designed to give immediate
17 notification to Class members;
- 18 iii. Disgorgement and/or the imposition of a constructive trust upon
19 Defendants' ill-gotten gains, thereby freezing Defendants' assets,
20 and/or requiring Defendants to pay restitution to Plaintiff and all
21 members of the Class of all funds acquired by means of any act or
22 practice declared by this Court to be an unlawful or unfair business
23 practice, a violation of federal or state statutes, or to constitute unfair
24 competition; and

25 E. Award Plaintiff and the Class their costs of suit, including reasonable
26 attorneys' fees as provided by law.

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28

XIV. JURY DEMAND

186. Pursuant to Fed. R. Civ. P. 38, Plaintiff, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: March 23, 2018

Respectfully Submitted,
JOSEPH SAVERI LAW FIRM, INC.

By: /s/ Joseph R. Saveri
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